



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,506	05/25/2001	Ghita Lanzendorfer	BEIERSDORF70	8673

7590 08/07/2003

Norris McLaughlin & Marcus
220 East 42nd Street
30th Floor
New York, NY 10017

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 08/07/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/744,506

Applicant(s)

LANZENDORFER ET AL.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,9 and 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1617

DETAILED ACTION

Claims 8-9, 16-23 are pending. The Amendment filed 5/23/03, Paper No. 14, amended claims 8 and 18, and cancelled claims 13-14.

It is respectfully noted that the Amendment filed 5/23/03, Paper No. 14, identified claims 8 and 18 as previously amended. However, the Amendment filed 5/23/03 "currently amended" claims 8 and 18.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/23/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claim 9 is vague and indefinite, as it is confusing.

Art Unit: 1617

1. Why are antioxidants listed twice in the Markush group?

2. What are UVA/UVB filter substances? Is such a substance anything that screens sun, such as hats or blankets? The Examiner respectfully suggests that Applicant substitute the term “compounds” with the term “substances”

Regarding this rejection, Applicant argues, “The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claim unclear”. This argument is not persuasive, as instant claim 9, twice recites the term “antioxidant”. Such a repetition is redundant and is confusing, as it is not clear what Applicant intends by reciting the term “antioxidant” twice in the claim.

Applicant argues, “breadth of a claim is not to be equated with indefiniteness. . . maintaining this rejection would appear to cast aspersions on previously issued US patents, e.g. U.S. Patent 6,531,117”. This argument is not persuasive. As pointed out by Applicant, the Examiner will not comment on the patentability of claims in a US patent. Furthermore, it is respectfully pointed out that the prosecution of every patent Application is distinct.

The Examiner contends that the term “substance” is vague and indefinite. What is a substance? The specification does not define this term and one of ordinary skill in the art would not be apprised of its meaning. Thus, the metes and bounds of this claim are unascertainable.

(ii) The phrase “wherein the encapsulated form is solution form” in claim 18 is vague and indefinite, as it is confusing. How can an encapsulated form be a solution form? How can the composition of claim 8 take on two forms? Does Applicant mean that the encapsulated form is a solution? If so, the Examiner respectfully suggests that Applicant amend the claim to recite, “wherein the encapsulated form is a solution”. Or does Applicant intend to recite the preparation

Art Unit: 1617

of claim 8, wherein the preparation is encapsulated, and wherein the preparation is in the form of a liquid. If so, the Examiner respectfully suggests that Applicant amend claim 16 to recite, "wherein the preparation is encapsulated"; amend claim 17 to recite, "wherein the preparation is encapsulated by materials selected from the group consisting of . . ."; amend claim 18 to recite "wherein the preparation is in the form of a solution".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caserio et al.

The instant invention is directed toward a composition comprising 0.01-0.5% of a bile acid or salt, wherein the bile acid is selected from dehydrocholic acid, lithocholic acid, cholic acid, glycocholic acid, taurocholic acid, ursodeoxycholic acid, and taurocholic acid, and method of applying the composition to the skin.

Caserio et al. teach a cosmetic composition which is suitable for application to the skin or hair which comprises 0.1-20% of a cholanic acid derivative and a powder absorbent. Optionally, water and/or other liquid carriers can be incorporated in the composition. Lithocholic acid, dexodeoxycholic acid, and cholic acid are taught as preferred cholanic acid derivatives. Emollients, propellants, organic solvents, humectants, and thickeners are taught as cosmetically acceptable carriers. Antioxidants are taught as ingredients that can be added to the composition.

Art Unit: 1617

Exemplified is a composition comprising 5% taurocholic acid and cosmetic auxiliaries. The reference lacks an exemplification of a preferred bile acid comprising 0.01-0.5% of the composition and the percent weight of antioxidants. See abstract; Col. 1, line 66-Col. 2, line 37; Col. 3, lines 64-66; Col. 4, lines 6-11; Col. 6, line 59-Col. 7, line 11; Col. 8, line 13-Col. 8, line 50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the cholanic acid derivatives, taught by Caserio et al., as comprising 0.1-0.5% of a composition because Caserio et al. teach that the cholanic acid derivatives comprise from 0.1-20% of the composition and because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the antioxidants of Caserio et al. as comprising 1-10% of the composition because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 105 USPQ 233) and because of the expectation of achieving a composition with optimum antioxidant effects.

Regarding the phrase "a barrier strength effective amount", it is respectfully pointed out that the instant invention teaches "a barrier strength effective amount" as 0.01-0.5% of a bile acid or salt thereof, and Caserio et al. teach bile acids in this amount. Thus, this limitation is met.

Art Unit: 1617

Claims 19-20 are directed to a method of applying a composition comprising 0.01-0.5% of a bile acid or salt thereof, wherein the bile acid is selected from dehydrocholic acid, lithocholic acid, cholic acid, glycocholic acid, taurolithocholic acid, ursodeoxycholic acid, or taurocholic acid, to the skin. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which must strengthen the barrier function of the skin, as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caserio et al. as applied to claims 8-9, 19-21 above, and further in view of Tisdale et al. (6,103,246).

Caserio et al. is applied as discussed above. The reference lacks encapsulated forms.

Tisdale et al. teach that liposomes penetrate into the deep underlying layers of the skin where they deliver their active agents in a time-release action. Liposomes are encapsulated preparation forms. See Col. 2, lines 38-59.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the liquid compositions of Caserio et al. in the form of liposomes, as taught by

Art Unit: 1617

Tisdale et al., because of the expectation of achieving a cosmetic composition with enhanced skin penetration and time-released action.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caserio et al. as applied to claims 8-9, 19-21 above, and further in view of Pittrof et al. (5,376,646).

Caserio et al. is applied as discussed above. The reference lacks vitamin E.

Pittrof et al. teach topical preparations containing the salt of a cholanic acid and a lipid for cosmetic use. Exemplified is a 2% tocopherol acetate mixed micelle solution comprising sodium glycocholate for topical use. See Col. 6, line 60-Col. 7, line 12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the tocopherol acetate taught by Pittrof et al. to the composition of Caserio et al. because Caserio et al. teach that antioxidants can be added to their composition and Pittrof et al. teach tocopherol acetate as an antioxidant that can be combined with bile acid salts; thus, one of skill in the art would be motivated to look to Pittrof et al. for antioxidants that are combinable with bile acid salts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Application/Control Number: 09/744,506

Page 8

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
July 1, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER